IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

DANIEL HUBERT, individually and on behalf of all others similarly situated,	:	Civil Action No. 2:15-cv-01391-MRH
Plaintiff,	:	Oral Argument Requested
v.	:	This Document Relates
GENERAL NUTRITION CORPORATION,	:	All Actions
Defendant.	:	
(In re: GNC Picamilon/BMPEA Litigation)	:	

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS FIRST AMENDED CONSOLIDATED COMPLAINT

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Plaintiffs, on behalf of themselves and members of the putative class, submit the following opposition to Defendant General Nutrition Corporation's ("GNC") Motion to Dismiss First Amended Consolidated Complaint ("Motion" or "Mot.").

I. INTRODUCTION

Plaintiffs' First Amended Consolidated Class Action Complaint ("CAC" or "Complaint") alleges Defendant General Nutrition Corporation's ("GNC" or "Defendant") violations of state consumer protection and false advertising statutes, unfair competition law, breach of warranty, negligent misrepresentation, and unjust enrichment based on Defendant's marketing and sale of mislabeled supplements containing picamilon, BMPEA, and *acacia rigidula* (collectively "the Ingredients"), which are not even legally available in prescription drug form in the United States, much less as ingredients in dietary supplements. Having been caught red-handed, Defendant responds with a Motion to Dismiss that largely ignores or misconstrues a number of inconvenient facts in the hope that they will go away. For example, Defendant was well aware as early as 2007 that the Ingredients were not lawful dietary ingredients under the Food, Drug and Cosmetic Act ("FDCA"), and that serious questions had been raised regarding their safety, but nonetheless continued to market and sell the products for some time thereafter. Defendant also ignores the fact that it failed to submit a new dietary ingredient notification ("NDI") to the Food and Drug Administration ("FDA") for sale of products containing the Ingredients, a legal prerequisite for selling any products containing ingredients not marketed prior to October 15, 1994, as was the case with the Ingredients.

Notably, Defendant does not contest and thus concedes that Plaintiffs have met their pleading requirements under Fed. R. Civ. P. 8(a) and 9(b). Faced with allegations that are more than sufficient to satisfy Plaintiffs' pleading requirements, Defendant makes a number of legal arguments that have either been rejected by numerous courts or have apparently never been attempted due to their utter lack of legal basis. For example, courts have frequently rejected Defendant's argument that Plaintiffs lack standing absent allegations of physical injury; the economic injury of overpaying for a mislabeled product is sufficient.

Defendant's contention that Plaintiffs' claims are preempted by the FDCA has also been rejected. Preemption does not apply where, as here, a suit is based on violations of state consumer protection and false advertising laws, not the FDCA itself, and the state-law requirements at issue parallel the requirements of the FDCA. Plaintiffs' claims are also not preempted due to their failure to use a "12-sample methodology" to test for the level of the BMPEA in certain of the products at issue because Plaintiffs do not claim that Defendant inaccurately disclosed the amount of BMPEA in these products but, instead, failed to disclose that BMPEA was present in the products *at all*.

Defendant next claims that a final FDA action must be reached regarding the legality of the Ingredients before this suit can proceed, but this is incorrect because, *inter alia*, agency action is not a prerequisite or a requirement for a private plaintiff to bring a parallel claim seeking relief for consumer harm. It would also be highly inequitable to require agency action prior to Plaintiffs' suit in light of Defendant's failure to pursue the pre-market notification process despite being aware, as early as 2007, that certain of the Ingredients were not yet permitted to be sold under the FDCA.

Defendant also argues, without a shred of authority, that the "FDA Guarantee" provides Defendant immunity from liability because it purportedly received "good faith guarantees" of the legality of the products at issue from its manufacturers. But this argument fails because, among other reasons, the so-called "guarantee" only applies to allegations of criminal malfeasance, as Defendant itself concedes.

Finally, Defendant has filed a declaration by one of its employees that is filled with hearsay, rank speculation and improper factual assumptions in Defendant's own favor. This declaration should be rejected in its entirety, and only serves to demonstrate that there are issues of fact making denial of Defendant's Motion appropriate.[1]

[1] Defendant relies on the Declaration of GNC employee Stephen Cherry (the "Cherry Declaration"), which contains a highly improper mixture of hearsay and claimed clairvoyance. The Cherry Declaration should be stricken for the reasons stated in the concurrently filed motion to strike. Defendant has also submitted a request for judicial notice

II. STATEMENT OF FACTS

Defendant GNC is the world's largest retailer of sports and dietary supplements. *See* ¶1.[2] Defendant markets and sells numerous types of supplements in stores throughout the United States, including supplements that contain picamilon, BMPEA and *acacia rigidula*. *See* ¶¶36, 38. Products containing these Ingredients have not been approved for sale in the United States, a fact that the FDA has recently reiterated. *See* ¶¶44, 49, 60, 67-70. Experts have also raised questions about the safety of consuming the Ingredients. *See* ¶¶45, 49, 57-59, 62-64, 67. Plaintiffs themselves even commissioned laboratory testing of *acacia rigidula* extract which confirmed that BMPEA did not naturally occur in the *acacia rigidula* sample. *See* ¶50.

Defendant has control over the labeling, production, and marketing of its vendors' products within its stores. *See* ¶¶73-74, 77, 82. Defendant was aware of the illegality and potential safety issues of the Ingredients since as early as 2007 (in the case of picamilon). *See* ¶¶4, 43-44, 52-55, 70. Despite this, even after becoming aware of the issues surrounding sale of products containing the Ingredients, Defendant continued to promote and sell such products while falsely holding them out to contain safe and legal "dietary ingredients." *See* ¶¶47, 55, 70. Apart from the present suit, Defendant's practices have led to, *inter alia*, a lawsuit by the Oregon Attorney General, as well as product recalls and bars on selling products containing certain of the Ingredients by Health Canada and the European Food Standards Agency. *See* ¶¶46, 51, 64.

III. STATUTORY BACKGROUND

In 1990, Congress amended the FDCA to address nutrition labeling for most food products. *See* National Labeling and Education Act of 1990 ("NLEA"), Pub L. No. 101-535, 104 Stat. 2353. In 1994, Congress again amended the FDCA with the enactment of the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325. Finished dietary supplement products and dietary ingredients are generally regulated as foods

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of certain materials attached to the Cherry Declaration and the declaration of Amy B. Alderfer, Dkt. No. 49-5 ("RJN"). Plaintiffs are submitting an opposition to the RJN concurrently with this brief.

[2] "¶" refers to the numbered paragraph of the CAC, Dkt. No. 40.

under the FDCA, as amended by DSHEA. *See* 21 U.S.C. § 321(ff). The FDCA defines a dietary ingredient as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. *Id*.

As a food, a dietary supplement may not be marketed if it is misbranded. *See* 21 U.S.C. § 343. Section 343 lists twenty-three reasons why a food "shall be deemed misbranded," several of which apply to dietary supplement labeling and advertising. *Id.* While these provisions largely address specific labeling features, the FDCA contains a catch-all provision that deems a product misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 343(a)(1). A product may be misbranded because its labeling is misleading "not only [on account of] representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations . . . ." 21 U.S.C. § 321(n).

In addition, a dietary supplement or ingredient may not be sold if it is adulterated. *See* 21 U.S.C. § 331(a), (b), (c) and (k). A dietary supplement is adulterated if it "presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A).

Although GNC appears to liken dietary supplements to drugs, *see* Mot. at 13, the analogy is inapt. Unlike drugs, dietary supplements are not intended to treat, diagnose, prevent, or cure diseases. *See* 21 U.S.C. § 321(g)(1) (defining drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"). Moreover, the FDA's regulation of food, including dietary supplements, is far less extensive than its regulation of drugs. The DSHEA does not require pre-market approval of supplements with dietary ingredients which were sold in the United States before October 15, 1994. *See* 21 U.S.C. § 350b(a)-(d). The FDA instead presumes these supplements are safe based on their longtime

public use and consumption. And, in contrast with drug labeling, the FDA does not preapprove dietary supplement labeling. *See id.*

Supplements containing a "new dietary ingredient," defined as an ingredient not marketed in the United States in a dietary supplement before October 15, 1994, are deemed to be adulterated under 21 U.S.C. § 342(f) unless (i) the dietary ingredient is present in the food supply as an article used for food in the same chemical form in which it is presented in the dietary supplement; or (ii) the manufacturer or distributor can show that the new ingredient will reasonably be expected to be safe under the conditions recommended or suggested in the labeling. *See* 21 U.S.C. § 350b(a). To make this evidentiary showing, the manufacturer or distributor must submit an NDI to the FDA establishing a reasoned basis for the new ingredient's safety profile. *See* 21 U.S.C. § 350b(a)-(b). The new dietary ingredient may be marketed or sold 75 days after the FDA publicly acknowledges receipt of the premarket application if it takes no action, but not before. *See* 21 U.S.C. § 350b(a).

IV. ARGUMENT

Defendant does not contest that Plaintiffs have satisfied their pleading requirements under Fed. R. Civ. P. 8 and 9(b) through their well-pled Complaint. Instead, Defendant's Motion raises a number of legal arguments that have either been previously rejected or apparently have never before been raised, likely due to their being unmoored from any legal authority. Defendant also seeks to resolve disputed facts in its favor contained in documents that Plaintiffs do not rely on in the CAC. These groundless arguments should each be rejected.

A. Plaintiffs Have Standing to Pursue Their Claims

Defendant argues that Plaintiffs lack Article III standing because Plaintiffs do not allege that they have suffered personal injury, or that they ever consumed the product. *See* Mot. at 11-13. However, this is a consumer protection action, not a personal injury action. Here the legally cognizable harm – economic injury – occurred at the time of purchase and not from the use of a product. This type of harm has long been held sufficient to confer Article III standing. *See*

Danvers Motor Co. v. Ford Motor Co., 432 F.3d 286, 293 (3d Cir. 2005) (Alito, J.) ("Monetary harm is a classic form of injury-in-fact.").

While injury-in-fact is a necessary component to establishing Article III standing, it "is not Mount Everest." *Danvers Motor*, 432 F.3d at 294 (citing *Bowman v. Wilson*, 672 F.2d 1145, 1151 (3d Cir. 1982)). Instead, the "contours of the injury-in-fact requirement, while not precisely defined, are very generous," and merely require the claimant to allege "some specific, 'identifiable trifle' of injury." *Bowman*, 672 F.2d at 1151 (quoting *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 690 n.14 (1973)). Here, the economic harm that Plaintiffs allege is not unique and is one of the "paradigmatic forms" of injury in fact. *Danvers Motor*, 432 F.3d at 291.

Plaintiffs, as purchasers of the Products, allege "injury in fact" in the form of economic injury as a result of purchasing products with false, misleading and inaccurate labeling, which omitted information material to Plaintiffs' purchases. In the CAC, Plaintiffs allege that Defendant has long been aware that the Ingredients are not lawful dietary ingredients, have no history of safe usage and cannot lawfully be sold in the United States. *See* ¶¶4, 43-44, 52-55, 70. Plaintiffs further allege that Defendant openly disclosed these unlawful Ingredients on the labels of the products at issue, which deceived and misled consumers into believing that products with these Ingredients were safe and could be legally sold when they could not. *See* ¶¶47, 51, 64-65, 72, 79, 83. Plaintiffs would not have purchased the Products had they known of the true nature and quality of the Products. *See* ¶¶6, 24.

In addition to *Danvers Motor* in the Third Circuit, *supra*, there is a considerable body of case law confirming that this type of economic injury confers Article III standing.[3] Here,

[3] *See Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 454 (E.D.N.Y. 2013) (consumers alleging economic injuries as result of purchasing supplements based on false, misleading, deceptive and unfair labeling, and who would not have purchased the products had the supplements been labeled accurately, sufficiently alleged injury-in-fact); *In re Hydroxycut Marketing and Sales Practice Litigation*, 801 F. Supp. 2d 993, 1002-03 (S.D. Cal. 2011) (consumers who purchased weight loss supplements allegedly presenting serious health risks had Article III standing to pursue claims despite not been physically harmed by the product); *In re Bayer Corp. Combination Aspirin Products Mktg. and Sales Practices Litig.*, 701 F. Supp. 2d 356 (E.D.N.Y. 2010) (consumers who purchased aspirin products with labels misrepresenting virtues of products had Article III standing, even though none suffered physical harm, as plaintiffs were injured by paying for product that delivered less than what was bargained for); *see also Chacanaca v.*

Plaintiffs' claims are straightforward and fit squarely within this well-established body of law that economic injury is a sufficient basis for standing. Like the plaintiffs in each of the cited cases, Plaintiffs seek, *inter alia*, the return of their purchase price because the Products could not lawfully be marketed and because Plaintiffs would not have purchased the Products had they known about their true nature and quality. *See* ¶¶6, 24. This "[e]conomic injury suffices as a form of injury-in fact that meets [the injury-in-fact] element of standing." *Hughes*, 930 F. Supp. 2d at 453 (citing *Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 161 (1981)).

Defendant also argues that Plaintiffs somehow lack standing because, at the time of the purchases complained of in the Complaint, the FDA had not acted in any way to question the use of the Ingredients. *See* Mot. at 11-13. But neither Plaintiffs' claims, nor their standing to bring them, are contingent upon FDA action. The FDA never approved the Ingredients for use in dietary supplements, including in the Products at issue. Therefore, the Products could not be lawfully sold at any time, either before or after the FDA issued its warning letters. As Plaintiffs allege, Defendant was long aware that the Products could not be legally sold to consumers. *See* ¶¶4, 43-44, 52-55, 70. In spite of this knowledge, Defendant nevertheless continued to sell the Products to Plaintiffs and Class members who were hoodwinked into purchasing these supplements with mislabeled and dangerous ingredients.

Defendant further argues that Plaintiffs do not have standing because there has never been any final agency action declaring the subject Ingredients unlawful. *See* Mot. at 13. This argument again misses the mark, as evidenced by Defendant's failure to cite a single case in support of its argument, and its admission that it has yet to provide any evidence in the Oregon Action that the Products were lawfully sold. *See also infra* Section IV.C. Accordingly, Plaintiffs have sufficiently demonstrated Article III standing.

The Quaker Oats Co., 752 F. Supp. 2d 1111, 1124-1125 (N.D. Cal. 2010) (consumers who purchased food products with deceptive and false labeling had Article III standing despite no physical harm because they alleged they would not have purchased products had they known true nature); *Askin v. Quaker Oats Co.*, 818 F. Supp. 2d 1081, 1083-84 (N.D. Ill. 2011) (consumer sufficiently pled injury in-fact after paying premium for product based on false claim that product was healthy despite no physical harm from product).

B. Plaintiffs' State-Law Claims Are Not Expressly or Impliedly Preempted

Defendant next argues that Plaintiffs' claims are preempted. *See* Mot. at 13-17.[4] To the contrary, Plaintiffs' consumer protection claims easily escape preemption because their suit is based on violations of state consumer protection and false advertising laws, unfair competition law, breach of warranty, negligent misrepresentation, and unjust enrichment—not the FDCA itself—and those state-law requirements parallel FDCA requirements. *See, e.g.*, *ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, No. 14-15180, 2016 WL 1460171, at *2 (9th Cir. Apr. 14, 2016) (holding FDCA does not preempt state unfair competition claim alleging dietary supplement falsely advertised as "DSHEA-compliant"). Moreover, Defendant's argument that Plaintiffs' claims are preempted because they failed to use the 12-sample methodology to allege nutrient content violations, *see* Mot. at 16-17, is also erroneous, as numerous courts have ruled.[5]

1. 21 U.S.C. § 343-1 Does Not Expressly Preempt Plaintiffs' Parallel State-Law Claims

[4] Although Defendant seeks dismissal of all claims based on preemption, the preemption doctrine does not even apply to claims based on other federal statutes, such as Plaintiffs' Magnuson-Moss claim. *See POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014) (distinguishing between preclusion and preemption doctrines). In any event, there is no basis to find that the FDCA is in irreconcilable conflict with the Magnuson-Moss Act. *See id.* at 2239 (Lanham Act case explaining that the FDCA's exclusive federal enforcement authority "does not indicate that Congress intended to foreclose private enforcement of other federal statutes"). Because Defendant has not argued otherwise, any such argument is forfeited.

[5] The preemption doctrine is rooted in the Supremacy Clause of the United States Constitution. *See* U.S. Const. art. VI, cl. 2. Federal law can preempt state law in three ways: express preemption, field preemption, and conflict (implied) preemption. *See Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985). Here, Defendant raises only express and implied preemption theories. Preemption is ultimately a question of Congress' intent. *See Wyeth v. Levine*, 555 U.S. 555, 565 (2009). In all preemption cases, "because the States are independent sovereigns in our federal system, . . . [courts] assum[e] that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *CTS Corp. v. Waldburger*, 134 S. Ct. 2175, 2188 (2014), *reh'g denied*, 135 S. Ct. 23 (2014) (internal quotations and citations omitted). That presumption is particularly strong here given the long history of state regulatory authority over food products, *see Plumley v. Mass.*, 155 U.S. 461, 472 (1894) (recognizing state authority to regulate "fraud and deception in the sale of food products"); and given that preemption here would leave consumers of fraudulent and deceptive food products without a remedy. *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 240 (2011) (recognizing the Court's longstanding doubt that Congress would quietly eliminate state remedies without providing a federal substitute); *see also Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 338 (3d Cir. 2009) (applying the presumption against preemption in rejecting field preemption under the NLEA).

The FDA and the States share regulatory authority over the marketing and sale of food, including dietary supplements. Congress addressed the precise scope of federal and state authority in an express preemption clause that identifies specific areas in which federal requirements preempt non-identical state-law requirements. *See* 21 U.S.C. § 343-1; *Hoffman v. Nordic Nats., Inc.*, No. 12-CV-05870 SDW MCA, 2014 WL 1515602, at *3 (D.N.J. Apr. 17, 2014) ("NLEA's preemption provision applies to the labeling of dietary supplements."). "[T]he plain wording" of this law "necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

The plain text of the statute bars States from adopting "any requirement for the labeling of food," such as dietary supplements, "that is not identical to the requirements" specifically identified therein. 21 U.S.C. § 343-1. Section 343-1 thus *only* preempts state-law requirements that are not identical to certain federal requirements given preemptive status by the FDCA. Congress reinforced this reading through Section 6(c)(1) of the NLEA, by instructing that the FDCA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under" Section 343-1. Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (codified as amended at 21 U.S.C. § 304-1 note). Courts therefore may not find implied preemption based on any provision of the NLEA. *See Holk*, 575 F.3d at 336.

Courts and the FDA widely agree that "the only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements on matters that are covered by" Section 343-1. *Chacanaca*, 752 F. Supp. 2d at 1118 (quoting Final Rule, 60 Fed. Reg. 57076, 57120 (Nov. 13, 1995)). As a result, Section 343-1's preemptive sweep is "narrow." *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). This reflects the fact that "Congress was cognizant of the operation of state law and state regulation in the food . . . field, and it therefore enacted limited exceptions in NLEA." *Holk*, 575 F.3d at 338.

Critically, the federal requirement that forbids manufacturers or distributors from marketing or selling "misbranded" food, which is defined in part as food with false or misleading labeling in any particular, 21 U.S.C. § 343(a)(1), is *not* among those federal requirements

identified by Congress as having preemptive effect. *See id*. § 343-1(a); *ThermoLife Int'l*, 2016 WL 1460171, at *2. This means that Section 343-1 does not bar a state-law claim that a dietary supplement label is false or misleading as a whole, or in a respect not specifically required or authorized by a federal statute or regulation given preemptive status by Congress.[6]

By preempting only those state requirements that are "not identical" to select federal requirements, Section 343-1 *permits* States to adopt requirements that are identical to federal requirements. *Turek*, 662 F.3d at 426 ("The state thus can impose the identical requirement or requirements, and by doing so be enabled, because of the narrow scope of the preemption provision in the Nutrition Labeling and Education Act, to enforce a violation of the Act as a violation of state law."); *see also* Remarks of Rep. Waxman, 136 Cong. Rec. 1539 (daily ed. July 30, 1990) ("Congress did not intend to alter the status quo, *i.e.*, states may choose to permit their residents to file unfair competition or other claims based on the violation of state laws."). This understanding of Section 343-1, moreover, fully accords with the Supreme Court's interpretation of similar preemption provisions. *See Reynolds v. Wal-Mart Stores, Inc.*, No. 4:14CV381-MW/CAS, 2015 WL 1879615, at *10 (N.D. Fla. Apr. 23, 2015).[7]

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[6] *See Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1122 (C.D. Cal. 2009) ("[T]here is no preemption language under § 343-1 which addresses a false or misleading label or, for that matter, the breadth of issues indicated by an unfair competition law."); *Chavez v. Blue Sky Natural Bev. Co.*, 268 F.R.D. 365, 370 (N.D. Cal. 2010) (Section 343-1 "do[es] not include the relevant prohibition on 'false or misleading' labeling set forth in 21 USC § 343(a)" and "therefore does not preempt the claims arising from false or misleading labels[.]").

[7] For example, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court considered the preemptive scope of 21 U.S.C. § 360k, an FDCA provision prohibiting States from establishing "any requirement . . . different from, or in addition to, FDCA labeling and design requirements for medical devices." The Court held that Section 360k does not preempt "[s]tate or local requirements that are equal to, or substantially identical to, requirements imposed by or under the [FDCA]." 518 U.S. at 496-97 (quoting 21 C.F.R. § 808.1(d)(2)). The Court also unanimously agreed that Section 360k permits States "to provide a traditional damages remedy for violations of" those identical state requirements. *Id*. at 495; *see id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The Court later reaffirmed this understanding of Section 360k in *Riegel v. Medtronic, Inc*., 552 U.S. 312, 330 (2008): "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Another example is *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), where the Supreme Court considered the preemptive reach of a provision prohibiting States from adopting "any requirements . . . in addition to or different from those required" by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq*. The Court held that "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id*. at 447. It also held that "although FIFRA does not provide a federal remedy to farmers and others who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy." *Id*. at 448.

States, to be sure, provide remedies for violations of requirements that mirror the FDCA. For example, States have enacted "Little Food" Acts, which generally adopt FDCA provisions wholesale, and which are actionable under causes of action such as state unfair competition laws. *See, e.g., In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1179 (Cal. 2008) (claims predicated on California's Sherman Law not preempted by FDCA because Sherman Law contains requirements identical to FDCA); *Reynolds*, 2015 WL 1879615, at *10 ("The Florida Food Safety Act ('FFSA') is in lockstep" with the FDCA; "[a] violation of the FFSA is actionable by a private party under causes of action such as [the Florida Deceptive and Unfair Trade Practices Act]"); *see also* ¶35 (listing state Food Acts applicable here).

More generally, States have regulated food and dietary supplement labeling through statutes and common law addressing unfair competition, deceptive business practices, false or misleading advertising, fraud, breach of warranty, negligent misrepresentation, and unjust enrichment—any of which may provide a remedy for false or misleading labeling, and all of which impose duties consistent with the federal "catch-all" barring false or misleading food labeling "in any particular." 21 U.S.C. § 343(a)(1).[8] These state-law duties need not be expressed in language identical to Section 343-1 or its animating regulations, and need not incorporate federal standards as an element of a cause of action in order to survive preemption. *See Bates*, 544 U.S. at 454 ("To survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding [Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)] requirement; indeed, it would be surprising if a common-law requirement used the same phraseology as FIFRA"); *see id*. at 447 ("state law need not explicitly incorporate FIFRA's standards as an element of a cause of action in order to survive pre-emption").[9]

[8] That *acacia rigidula* is adulterated underscores the materiality of the misrepresentations or omissions.

[9] *See also Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) ("While there may not be a 'traditional state tort law' claim for an 'adulterated' product in so many words, the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law. The evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient.").

Plaintiffs' Complaint asserts precisely such parallel claims under state consumer protection and false advertising acts, unfair competition law, Little Food Acts, breach of warranty, negligent misrepresentation, and unjust enrichment—all of which escape preemption under Section 343-1. To the extent Defendant disagrees, its disagreement is extremely limited. Defendant identifies a single regulation, 21 C.F.R. § 101.9, as having preemptive application here (which it does not, for reasons addressed *infra* at Section IV.B.3). Defendant otherwise fails even to argue, let alone establish, that federal law renders non-misleading any other aspect of labeling or advertising challenged by Plaintiffs. This was Defendant's burden. *See In re Asbestos Products Liab. Litig. (No. VI)*, No. 14-1715, 2016 WL 2849331, at *5 n.6 (3d Cir. May 16, 2016) ("federal preemption is an affirmative defense on which the defendant bears the burden of proof"). At this point, any such argument is forfeited and cannot be resuscitated in a reply brief. *See United States v. Martin*, 454 F. Supp. 2d 278, 281 n.3 (E.D. Pa. 2006) (reply brief "is intended only to provide an opportunity to respond to the arguments raised in the response brief; it is not intended as a forum to raise new issues.").

2. 21 U.S.C. § 337(a) Also Does Not Preempt Plaintiffs' State-Law Claims

Notwithstanding Section 343-1, GNC argues that 21 U.S.C. § 337(a) impliedly preempts Plaintiffs' suit. This argument, however, is premised on the falsehood that Plaintiffs are seeking to "directly enforce the FDCA." Mot. at 16. Not so, as Plaintiffs' suit is based on violations of state law, not the FDCA itself. *See Turek*, 662 F.3d at 426 (explaining Congress' choice to allow states to impose identical requirements is "important" because FDCA does not create private right of action).

Contrary to Defendant's suggestion, nothing in Section 337's text remotely suggests it bars actions under state law. Section 337(a) provides that "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Section 337(b), in turn, authorizes a State to file an action to enforce certain provisions of the FDCA, provided the State satisfies procedural requirements which ensure

coordination with the FDA. *See* 21 U.S.C. § 337(b). The FDA recognized, in promulgating regulations to implement Section 337(b), that Section 337 "applies only to proceedings to enforce the [FDCA]" but "does not prohibit a State from enforcing identical State law." State Enforcement Provisions of the Nutrition Labeling and Education Act of 1990, 1993 WL 1544, 58 Fed. Reg. 2457-01, 2458 (Jan. 6, 1993).

Courts agree that Section 337 does not prohibit a State from allowing *private* suits to enforce parallel state requirements. *See, e.g.*, *Turek*, 662 F.3d at 426; *Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 957 (N.D. Cal. 2013) ("Congress did not intend to preclude private enforcement actions of state laws that mirror the FDCA.") (citations omitted). These courts' reasoning is unimpeachable. Congress, in Section 343-1, expressed an intention to permit States to adopt parallel food-labeling requirements, and nothing in Section 337 preempts or otherwise limits suits by States to enforce parallel state law. Given that Section 337(b)'s limitations on a State's direct enforcement of the FDCA do not preempt or limit a State's enforcement of parallel state requirements, neither can Section 337(a)'s restrictions on private enforcement of the FDCA plausibly bar a State from allowing private suits based on parallel state requirements. *See In re Farm Raised Salmon Cases*, 175 P.3d at 1184 (finding "no persuasive rationale to explain why private claims based on these same state laws would be of any greater concern to Congress than California's enforcement of state laws—in both instances, state laws identical to the FDCA are enforced without first notifying the FDA"). Especially in light of the presumption against preemption, which has particular force here, *see Holk*, 575 F.3d at 338, there is no basis to conclude that Congress, in enacting the FDCA, clearly and manifestly intended to preempt claims where the state-law duty parallels the federal-law duty. *See Turek*, 662 F.3d at 426; *see also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1231 (9th Cir. 2013) (en banc) (rejecting FDCA preemption of parallel state-law claims against medical device manufacturer).

Despite Defendant's mischaracterizations, Plaintiffs' action to enforce state laws that impose requirements which parallel FDCA requirements is fundamentally a state-law action, not an action to enforce the FDCA. Insofar as Plaintiffs' Complaint addresses federal law, it does so

simply to acknowledge that Plaintiffs' claims parallel federal requirements. Plaintiffs could easily remove every reference to federal law in their pleading and they would still plead valid state-law causes of action. To take one example, Plaintiffs' unfair competition claim based on violations of California's Sherman Law—in part, that the dietary supplement labeling at issue falsely or misleadingly asserts that picamilon, BMPEA, and *acacia rigidula* are dietary ingredients, *see* Cal. Health & Safety Code § 110660—mirrors the FDCA's requirement that labeling may not be false or misleading in any particular. *See* 21 U.S.C. § 343(a)(1). Even though the state-law claim mirrors the federal claim, Plaintiffs may prove a violation of California's Sherman Law without even referring to the FDCA.

Of course, Plaintiffs can also prove a violation of California's Sherman Law by proving a violation of the FDCA. *See* Cal. Health & Safety Code § 110100(a). Indeed, the Complaint asserts that Defendant violated federal law in addition to state law. *See, e.g.*, ¶ 5 (alleging GNC's actions are "in violation of state and federal law"). But that does not transform Plaintiffs' state-law claim into a federal claim. As the Supreme Court explained in *Lohr*, state-law claims predicated on violations of the FDCA nonetheless remain *state-law* claims. In fact, in *Lohr* the Supreme Court held that the FDCA did not preempt state-law claims which included allegations that the defendant had "violated FDA regulations." 518 U.S. at 495. Subsequently, in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court explicitly rejected an "attempt to characterize . . . the claims at issue in [*Lohr*] . . . as 'claims arising from violation of FDCA requirements.'" *Id*. at 352. This was a mischaracterization, the Court in *Buckman* explained, because the claims in *Lohr* arose from a state-law duty, "not solely from the violations of FDCA requirements." *Id*. Plaintiffs, as "master[s]" of their complaints,*The Fair v. Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913) (Holmes, J.), may sue only under state law whether or not the same allegations would support a federal cause of action. *See Merrell Dow Pharmaceuticals*

v. Thompson, 478 U.S. 804, 809, 827 n.6 (1986). That is precisely what Plaintiffs have done here.[10]

Notably, Plaintiffs' state-law claims do not simply require proof of a state-law violation that parallels the FDCA. Plaintiffs must also establish additional elements, such as damage or injury resulting from the violation. *See, e.g.*, Cal. Bus. & Prof. Code § 17204 (requiring proof of injury-in-fact and loss of money or property as a result of unfair competition); *Dougherty v. Bank of Am., N.A.*, No. 2:15-CV-01226-TLN-CKD, 2016 WL 1337536, at *8 (E.D. Cal. Apr. 5, 2016) (negligent misrepresentation requires proof of justifiable reliance and resulting damages). That Plaintiffs must establish these additional elements further demonstrates that they are not seeking to enforce the FDCA but instead parallel state-law duties which the FDCA does not preempt. *See Lohr*, 518 U.S. at 495 (state-law claims are not "different from" federal requirements for preemption purposes simply because plaintiffs must prove additional elements to prevail under state law).

Defendant appears to suggest that Plaintiffs' state-law claims are impliedly preempted under *Buckman*. *See* Mot. at 14 (citing *Riley*, 625 F. Supp. 2d at 777, which cites *Buckman*). But *Buckman* held only that a "fraud-on-the-FDA" claim against a regulatory consultant who had no dealings with plaintiffs but had helped a manufacturer obtain FDA approval for a medical device was preempted because it interfered with FDA's discretion about whether and how to exercise its federal enforcement authority. *See* 531 U.S. at 350-53. Here, Plaintiffs are not suing for fraud on the FDA, but for GNC's false and misleading representations or omissions which

[10] Defendant's authorities do not demonstrate that Plaintiffs' claims are preempted. *See* Mot. at 14 (citing *Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 777 (D. Minn. 2009), and *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Prac. Litigation*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010)). *Riley* simply observed that "*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." 625 F. Supp. 2d at 777. *In re Bayer* made the same observation. 701 F. Supp. 2d at 369 (citing *Riley*). The Seventh Circuit in *Bausch* subsequently explained that "[r]egardless of how wide or narrow the gap" between express or implied preemption may seem, this observation "reflect[s] the limits of both *Buckman* and *Lohr*." 630 F.3d at 557-58 (considering medical device preemption under Section 360k). Read together, *Buckman* and *Lohr* establish that recognized state-law claims which parallel federal claims are *neither* expressly *nor* impliedly preempted by the FDCA. *Id*. at 558. Nothing in *Riley* or *In re Bayer* suggests otherwise.

injured them. Nor are they suing to enforce the FDCA, but instead under longstanding state-law causes of action for deception in food labeling. Defendant's preemption defense "injects FDCA compliance questions into the case, but that does not make this a backdoor private enforcement action."[11] *See* Br. for U.S. as Amicus Curiae, 2014 WL 827980, at *28, *POM Wonderful LLC v. The Coca-Cola Co.*, 134 S. Ct. 2228 (2014) ("Br. For U.S. as *Amicus Curiae* in *POM Wonderful*").

Defendant is also wrong to suggest that Plaintiffs cannot bring this state-law suit unless and until the FDA determines that GNC violated the FDCA.[12] *See* Mot. at 15. For one thing, the FDA's failure to initiate an enforcement action cannot be construed as implicit approval.[13] *See Altria Grp., Inc. v. Good*, 555 U.S. 70, 89-90 (2008) ("agency nonenforcement of a federal statute is not the same as a policy of approval") (citing *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002)). For another, Congress' decision not to preempt parallel state-law claims, *see* 21 U.S.C. § 343-1, reflects its considered judgment that state regulation of food and dietary supplement labeling is a complementary form of regulation which offers "an additional, and important, layer of consumer protection." *See Wyeth*, 555 U.S. at 579 (2009) (rejecting FDCA preemption of failure-to-warn suits against brand-name prescription drug manufacturers); *Bates*, 544 U.S. at 451 ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA."). Parallel state-law actions, therefore, do not

[11] And here, unlike in *Buckman*, 531 U.S. at 350-51, Plaintiffs' suit does not concern the FDA's approval of a product or any other FDA determination. In fact, as previously discussed, the FDA does not even pre-approve dietary supplement labeling. Therefore, any concern expressed in *Buckman* about skewing the FDA's medical device approval process is not presented by this state-law suit concerning dietary supplements.

[12] Though Plaintiffs' Complaint refers to FDA Warning Letters, which are not final agency action, those references neither alter the state-law character of Plaintiffs' claims nor are objectionable given that these warning letters relate to Plaintiffs' state-law injuries. *See Cline v. Advanced Neuromodulation Sys., Inc.*, 921 F. Supp. 2d 1374, 1381 (N.D. Ga. 2012) (plaintiff used warning letter to "allege[ ] specific facts about when and how these violations occurred in the manufacture of the specific device at issue"); *see also Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 156 (S.D.N.Y. 2011) (plaintiff used warning letter to support allegations that her medical device "was adulterated because some of the components, as a result of the manufacturing process, contained excess levels of manufacturing residue").

[13] The FDA, moreover, does not have a process for approving particular dietary supplement labeling, it does not accept formal petitions to take discretionary enforcement action, *see* 21 C.F.R. § 10.30(k), and its decision whether to initiate an enforcement action would not be subject to judicial review. *See Heckler v. Chaney*, 470 U.S. 821, 837-38 (1985).

depend on FDA's enforcement of FDCA requirements. *See ThermoLife Int'l*, 2016 WL 1460171, at *1 (rejecting argument that plaintiff must demonstrate FDA itself found an underlying FDCA violation to prevail on claim that dietary supplement distributor falsely advertised its products as "legal" or "DSHEA-compliant").

For all these reasons, Section 337 does not preempt Plaintiffs' state-law claims.

3. Plaintiffs' Claims Are Not Preempted by the Failure to Allege 12-Sample Testing

Defendant's final preemption defense, based on 21 C.F.R. § 101.9(g)(2), also fails. *See* Mot. at 16-17. This preemption argument concerns Plaintiffs' allegations that certain dietary supplement labeling failed to disclose that BMPEA was present in the supplement.[14] *See, e.g.*, ¶52. As the Complaint recounts, Plaintiffs commissioned tests of these products using LC/MS (Liquid Chromatography coupled to Mass Spectrometry) and GC/MS (Gas Chromatography coupled to Mass Spectrometry) methodologies. This testing confirmed that BMPEA is in fact present in certain *acacia rigidula* supplements. *See* ¶50.

GNC incorrectly contends that Plaintiffs were required to use a "12-sample methodology" identified in 21 C.F.R. § 101.9(g)(2) to test the level of BMPEA, and that their failure to do so means their claims regarding the absence of BMPEA are preempted. GNC both misunderstands the regulations and is mischaracterizing Plaintiffs' claims.

Under 21 C.F.R. § 101.13, "[a] claim that *expressly or implicitly* characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation . . . ." 21 C.F.R. § 101.13(b) (emphasis added). Section 101.9(g)(2) sets forth a methodology by which the *FDA* measures compliance with nutrient content claims on labeling. *See* 21 C.F.R. § 101.9(g)(2).[15] Manufacturers, however, are

[14] Other dietary supplement labeling did disclose the presence of BMPEA but identified BMPEA as a dietary ingredient, which it is not. *See* ¶65.

[15] What is more, only statements outside of the nutrition label are considered nutrient content claims subject to 21 C.F.R. § 101.13 and, in turn, Section 101.9. *See Reid v. Johnson & Johnson*, 780 F.3d 952, 960 (9th Cir. 2015).

"not preclude[d] . . . from using alternative analytical methods for determining nutrient content label values." 58 Fed. Reg. 2302-1, 2311.

Here Defendant has made *no* "express[] or implicit[]" characterization as to the level of BMPEA in certain dietary supplement labeling; rather, it failed to disclose the material fact that these supplements contain any BMPEA. Plaintiffs' allegation, then, is not that the nutrient content of BMPEA *as disclosed* was inaccurate; rather, Plaintiffs' allegation is that, for certain dietary supplements, BMPEA was *not* disclosed *anywhere*, whether in labeling or advertising. Thus Plaintiffs' claim that the labeling is false or misleading on its face in violation of 21 U.S.C. § 343(a) can be established without applying the testing methodology of Section 101.9(g)(2), which is solely the method by which the FDA tests whether an explicit or implicit nutrient content claim subject to 21 C.F.R. § 101.13 is accurate. *See* 21 C.F.R. § 101.9(g)(2); *cf. Gubala v. CVS Pharmacy, Inc.*, No. 14 C 9039, 2016 WL 1019794, at *9-10 (N.D. Ill. Mar. 15, 2016) ("*CVS Pharmacy*") (suggesting Section 101.9(g)(2) may not apply where the product is misbranded on its face). Section 101.9(g)(2) is therefore inapposite and provides no basis for preemption.

Even where Section 101.9(g)(2) applies, court have refused to find preemption at the pleading stage. Courts instead hold that plaintiffs may rely on testing results other than the 12-sample methodology to plead, with plausibility, that labeling overstates or understates nutrient content. *See CVS Pharmacy*, 2016 WL 1019794, at *8; *Gubala v. HBS Int'l Corp.*, No. 14 C 9299, 2016 WL 2344583, at *4 (N.D. Ill. May 4, 2016) ("Plaintiffs are not required to plead compliance with § 101.9(g)(2) in order to survive a motion to dismiss[.]"); *Clay v. Cytosport, Inc.*, No. 15-CV-165 L DHB, 2015 WL 5007884, at *3-4 (S.D. Cal. Aug. 19, 2015) (same); *Smith v. Allmax Nutrition, Inc.*, No. 1:15-CV-00744-SAB, 2015 WL 9434768, at *7-8 (E.D. Cal. Dec. 24, 2015) (same). As the court in *CVS Pharmacy* explained, "[w]hether independent testing along the lines of § 101.9(g)(2) confirms Plaintiff's [nutrient content] claim . . . is an issue of proof, and Plaintiff does not need to prove his case at the pleading stage of the case." 2016 WL 1019794, at *8. Here, Plaintiffs' testing more than suffices to establish, with requisite

plausibility, that certain dietary supplements in fact contained BMPEA, even if the precise amount of BMPEA has not been measured under the 12-sample methodology.

Defendant notes purportedly inconsistent rulings on this question, but as Judge Durkin in *CVS Pharmacy* explained, the authorities Defendant cites, *see* Mot. at 16, are either inapposite or not persuasive.[16] This Court, then, should follow the *CVS Pharmacy* line of authority, which properly applies pleading standards consistent with Third Circuit case law, thus allowing plaintiffs who performed some form of reliable testing to move past the initial pleading stage. *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 244 (3d Cir. 2012) (describing Rule 8 pleading standards).

Finally, even though Defendant bears the burden of persuasion on preemption, it offers no explanation why manufacturers can show regulatory compliance using other reliable methods, *see* 58 Fed. Reg. 2302-1, 2311, but Plaintiffs cannot show non-compliance using other reliable methods. Because Defendant has offered no interpretive authority to support its strained reading of FDA regulations, and because its interpretation is inconsistent with FDA's own comments, the Court should decline to dismiss any aspect of the Complaint based on Section 101.9(g). *See CVS Pharmacy*, 2016 WL 1019794, at *9.

For all these reasons, GNC's preemption defense fails in its entirety and the Complaint is not subject to dismissal, let alone dismissal with prejudice.

[16] *See CVS Pharmacy*, 2016 WL 1019794, at *7-8 & n.15 (finding *Burke v. Weight Watchers Int'l, Inc.*, 983 F. Supp. 2d 478, 483 (D.N.J. 2013), inapposite because it does not concern § 101.9(g)(2); finding *Vital v. One World Co., LLC*, No. SACV 12-00314-CJC (MLGx), 2012 U.S. Dist. LEXIS 186203, at *2, *13-18 (C.D. Cal. Nov. 30, 2013), distinguishable because the court did not decide preemption on the pleadings but converted the defendant's motion to dismiss to a motion for summary judgment and gave the plaintiffs a 45-day extension of time to conduct discovery; finding *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304 (E.D. Cal. 2014), *Mee v. IA Nutrition, Inc.*, No. C-14-5006-MMC, 2015 WL 2251303, at *4 (N.D. Cal. May 13, 2015), and similar cases unpersuasive because independent testing along the lines of Section 101.9(g)(2) is sufficient to plausibly allege a violation).

C. Neither Final Agency Action Nor Due Process Issues Preclude Plaintiffs' Suit

1. FDA's Enforcement of the FDCA is Not Required in Order for Plaintiffs to Bring Parallel State Claims Seeking Relief for Consumer Harm

Defendant contends that final enforcement action by the FDA is required before Plaintiffs can bring this suit, and that Plaintiffs cannot establish final agency action through the Welch Declaration or warning letters. *See* Mot. at 17-21. These arguments misstate the law and Plaintiffs' position. As already discussed, Plaintiffs need not wait for final agency action to bring a claim seeking relief for consumer harm. *See supra* Section IV.B.2. And because final agency action is not required, Defendant's lengthy discussion of how the Welch Declaration and the warning letters do not qualify as final agency action is entirely beside the point.[17]

As with its preemption arguments, Defendant's request for dismissal pending final FDA action mischaracterizes Plaintiffs' suit. Plaintiffs' parallel state-law suit for consumer deception concerns whether Defendant's "statements [in labeling and advertising] are false and misleading *to relevant consumers*[.]" *Mut. Pharm. Co. v. Watson Pharm., Inc.*, No. CIV.A. 09-5421 (GEB), 2010 WL 446132, at *5 (D.N.J. Feb. 8, 2010) (emphasis added). This "is not a matter reserved for the FDA, but a matter that falls within the jurisdiction of th[e] Court." *Id.*; *see also In re Bayer Corp. Combination Aspirin Prods.*, 701 F. Supp. 2d at 370-71 (noting "FDCA and the state law consumer protection statutes serve complementary, though somewhat overlapping, roles").

Critically, even the *FDA* takes the position that:

> courts . . . are capable of interpreting the FDCA and FDA's food-labeling regulations, with appropriate deference to FDA's interpretation. *Indeed, that is a task courts must perform to determine whether a state-law claim is expressly preempted or to adjudicate an "identical" state-law claim. See* 21 U.S.C. 343-1(a); 21 C.F.R. 100.1(c)(4); *cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 453 (2005) (remanding to determine whether state-law labeling requirements were "equivalent" to federal statutory and regulatory

[17] As with preemption, Defendant does not separately address Plaintiffs' Magnuson-Moss claim, ¶¶ 92-104, in the course of requesting dismissal until there is final agency action. There is no basis to dismiss this federal claim, for the same reasons there is no basis to dismiss Plaintiffs' state-law claims: final agency action is not necessary. *See ThermoLife Int'l., LLC*, 2016 WL 1460171, at *1 (finding it is not necessary for the FDA itself to find a violation of FDCA in order to prevail on Lanham Act and state unfair competition claims).

> misbranding standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq.).

Br. for U.S. as *Amicus Curiae* in *POM Wonderful*, 2014 WL 827980, at *27 (emphasis added); *id.* at *27 n.11 ("To the extent FDA disagrees with a court's interpretation of an ambiguous FDCA provision or regulation, the agency can exercise its interpretive discretion through subsequent rulemaking or guidance.").[18] There is therefore no basis to dismiss this suit pending final FDA enforcement of the FDCA.

Not surprisingly, Defendant is unable to cite any authority requiring final agency action before a private plaintiff may bring suit against a private defendant for misrepresentations under state law, including consumer protection statutes. On the contrary, Defendant's proffered cases on this subject nearly all involve suits brought to prevent or challenge agency actions.[19] The sole exception is *Ballentine v. United States*, 486 F.3d 806 (3d Cir. 2007), a voter's suit against the United States, which does not even involve an administrative agency and is otherwise completely inapposite.

Here it would be especially inappropriate to require final FDA action before Plaintiffs may proceed with their consumer suit. Defendant's own internal analysis demonstrates that it was aware since at least 2007 that picamilon is a "new dietary ingredient." *See* ¶¶43-44. Despite this knowledge, Defendant failed to invoke the pre-market notification process, which requires manufacturers and distributors who wish to market or sell supplements with "new dietary

[18] *See also id*. at *27-28 (noting the FDA's position that courts should not await agency determinations before proceeding with parallel claims because (1) there is no process to apply to the agency for discretionary review of food labeling, (2) agency action does not provide redress, and (3) court adjudication of such claims "tend to *reinforce*, not undo, the statutory and regulatory requirements") (emphasis in original).

[19] *See Bennett v. Spear*, 520 U.S. 154 (1997) (irrigation district sued Interior Dept. officials); *American Tel. & Tel. Co. v. E.E.O.C.*, 270 F.3d 973 (D.C. Cir. 2001) (employer's declaratory judgment against EEOC); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375 (9th Cir. 1983) (drug manufacturers' injunctive and declaratory judgment action against FDA enforcement); *Cody Laboratories, Inc. v. Sebelius*, 446 F. App'x 964 (10th Cir. 2011) (drug manufacturer's declaratory judgment action against FDA officials); *Trudeau v. Federal Trade Comm'n*, 456 F.3d 178 (D.C. Cir. 2006) (infomercial producer's injunctive and declaratory judgment suit against FTC challenging press release); *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726 (D.C. Cir. 2003) (sprinkler manufacturer's declaratory judgment action against CPSC); *Holistic Candlers and Consumers Assn. v. FDA*, 664 F.3d 940 (D.C. Cir. 2012) (candle manufacturers' injunctive action against FDA); *accord Dietary Supplement Coalition v. Sullivan*, 978 F.2d 560 (9th Cir. 1992) (dietary supplement manufacturers' declaratory judgment action against FDA).

ingredients" to notify the FDA. 21 U.S.C. § 350b(a). The failure to satisfy the notification requirements means that any product with a new dietary ingredient is adulterated *as a matter of law*. *Id*. Having utterly failed to notify the FDA when it had the obligation to do so, Defendant's request that the Court dismiss this suit in the absence of final FDA action is not offered out of respect for the FDCA. It is a litigation tactic. Worse, it is a completely unsound request, for the law neither requires final agency action before Plaintiffs may bring their parallel state-law claims seeking redress for consumer harm, *see ThermoLife Int'l*, 2016 WL 1460171, at *1; *Mut. Pharm. Co.*, 2010 WL 446132, at *5, nor does federal law even provide a mechanism to formally petition for discretionary enforcement. *See supra* n. 13 (citing 21 C.F.R. § 10.30(k) and *Heckler*, 470 U.S. at 837-38); *see also Reiter v. Cooper*, 507 U.S. 258, 268 n.3 (1993) (primary jurisdiction presupposes the parties may "apply to the [agency] for a ruling").

2. This Lawsuit Does Not Deprive GNC of Due Process

Defendant contends that Plaintiffs' suit deprives Defendant of its due process rights because, given that there was no final FDA action, Defendant was deprived of its right to challenge such action. *See* Mot. at 21-22. As discussed above, however, final agency action is not required in order for this Court to adjudicate parallel state-law claims. Defendant is otherwise being afforded all the process it is due. The CAC notifies Defendant of Plaintiffs' allegations regarding this mislabeling, and discovery will develop and provide further information. Defendant can attempt to challenge those allegations and litigate in this proceeding whether it mislead consumers through labeling and advertising.

Defendant's entire argument on this score also rests upon the claim that Plaintiffs allege that the warning letters and the Welch Declaration are "final agency actions." Mot. at 21. But Plaintiffs cite these materials as evidence in support of their consumer protection claims which Defendant will have an opportunity to rebut. Accordingly, Defendant is not being denied due process.

D. The "FDA Guarantee" is Inapplicable to Plaintiffs' Claims

Finally, Defendant asserts, without citation to a single case, that Section 303(c) of the FDCA immunizes it from any sort of civil liability. *See* Mot. at 22-23. But the defense is inapplicable as a matter of law because the statutory provisions Defendant relies upon only exempt innocent retailers from *criminal prosecution* under the FDCA and do not relieve the recipient of such a "guarantee" of civil liability or other consequences of selling misbranded food.

Despite attempting to utilize this argument as a basis to dismiss Plaintiffs' claims, Defendant fails to cite a single authority supporting its novel construction of the law, and the provision of the FDCA upon which it is based shows that "prosecution" is intended to have its ordinary meaning of criminal prosecution. The statute at issue, 21 U.S.C. § 333, has been in effect in one form or another for over 50 years, and at no point during its decades of existence has it ever been relied upon by any court as a basis for dismissing civil claims, nor has any published treatise or journal suggested such an effect.

The FDCA provides under the heading "[e]xceptions in certain cases of good faith, etc.," that "[n]o person shall be subject to the penalties of subsection (a)(1) of this section" for having received in good faith misbranded products if he can produce the required guaranty or undertaking. 21 U.S.C. § 333(c). The "penalties of subsection (a)(1)" are *criminal* penalties of imprisonment of not more than a year, a fine of not more than $1,000, or both. *See* 21 U.S.C. § 333(a)(1). The language of the statute could not be any plainer: Section 333 applies to *criminal* penalties only. Defendant concedes this, arguing merely that the "FDA Guarantee provides GNC with immunity from *misdemeanor prosecution* under the FDC act." Mot. at 22 (emphasis added). Defendant does not point to any language in the statute itself that supports any form of "civil immunity," and does not even try to analogize this statute with any similar statutes. In short, Defendant offers absolutely no support for its radical argument.

Additionally, even if Section 333(c) did provide some degree of civil protection, Defendant does not, and cannot, establish at this stage of the proceedings that it would be entitled

to such protection. Defendant simply represents to the Court that it "*can* establish that its third-party vendor agreements provide that the vendors warranted that the goods were manufactured, packaged, stored and shipped in accordance with the applicable standards promulgated under [all applicable laws]." Mot. at 22 (emphasis added). Promising the Court that it "can" establish this is utterly insufficient on a motion to dismiss and, at this point, Defendant has not proffered *any* of its agreements, much less all of them. It is not uncommon in the industry for a company such as Defendant to assume some authority over packaging, labeling and branding of the products supplied by third parties, and Plaintiffs have alleged just that. *See* ¶¶73-82. It is highly likely that discovery will reveal that Defendant is anything but an "innocent retailer," but at this stage of the litigation Defendant has provided no legal or factual rationale for why the "FDA Guarantee" should operate to bar any of Plaintiffs' claims.

V. CONCLUSION

For the reasons set forth above, Defendant's Motion to Dismiss the First Amended Consolidated Complaint should be denied in its entirety.[20]

[20] In the event the Court ultimately dismisses the CAC, or any claim therein, Plaintiffs reserve their right to seek to amend the Complaint pursuant to Fed. R. Civ. P. 15.

Dated: June 24, 2016

Respectfully submitted,

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